

"You've got all the opinions in. You've got the scientific opinion. You now have all the information you need. What is still holding up the decision?" Farr asked Dr. von Eschenbach.

Farr's inquiries came during a House Appropriations oversight hearing. He was spurred by the FDA's lack of action despite their own advisory committee's overwhelming conclusion that Plan B is safe, effective and should be approved for over-the-counter sales. Further, the Government Accountability Office reported last November that the FDA's review process for Plan B's over-the-counter application has been unusual and fraught with political interference.

When Dr. von Eschenbach could not lay out a timeline for a decision but promised that the process would continue to move forward, Farr bluntly stated, "The process has been moving forward for years...I would really appreciate a more direct answer on whether you think you can have this completed by the end of this year or by this summer." Dr. von Eschenbach demurred.

The FDA's most recent action on the Plan B application was to open a public comment period in August on the proposal to allow over-the-counter status for women aged 17 and older, while maintaining prescription-only status for women 16 and younger. Usually a comment period lasts 90 to 120 days, but for Plan B, the FDA chose a 60 day window which ended Nov. 1, 2005.

Farr asked Dr. von Eschenbach how many comments the agency received, what format the opinions came in and what kind of opinions were expressed. Unfortunately Dr. von Eschenbach was unable to answer. Instead he promised to get answers to Farr's Appropriations subcommittee at a later date.

"The bottom line is, we need a decision made because what you're doing is losing your credibility," Farr concluded during the hearing. "States are now releasing this drug over the counter through alternative mechanisms because the process has been so convoluted and so politicized here in Washington. It's time to step in and make a decision."

Emergency contraception has been available via prescription for more than 25 years and could prevent 1.5 million unintended pregnancies and 800,000 abortions each year in the U.S. Plan B is currently available over-the-counter in more than 30 countries around the world.